

toxins or excess fluid from the patient's blood using the principles of convection (via a high ultrafiltration rate) and/or diffusion (via a concentration gradient in dialysate). During treatment, blood is circulated from the patient through the hemodialyzer's blood compartment, while the dialysate solution flows countercurrent through the dialysate compartment. In this process, toxins and/or fluid are transferred across the membrane from the blood to the dialysate compartment. The hemodialysis delivery machine controls and monitors the parameters related to this processing, including the rate at which blood and dialysate are pumped through the system, and the rate at which fluid is removed from the patient. The high permeability hemodialysis system consists of the following devices:

(1) The hemodialyzer consists of a semipermeable membrane with an in vitro ultrafiltration coefficient ( $K_{uf}$ ) greater than 8 milliliters per hour per conventional millimeter of mercury, as measured with bovine or expired human blood, and is used with either an automated ultrafiltration controller or another method of ultrafiltration control to prevent fluid imbalance.

(2) The hemodialysis delivery machine is similar to the extracorporeal blood system and dialysate delivery system of the hemodialysis system and accessories (§ 876.5820), with the addition of an ultrafiltration controller and mechanisms that monitor and/or control such parameters as fluid balance, dialysate composition, and patient treatment parameters (e.g., blood pressure, hematocrit, urea, etc.).

(3) The high permeability hemodialysis system accessories include, but are not limited to, tubing lines and various treatment related monitors (e.g., dialysate pH, blood pressure, hematocrit, and blood recirculation monitors).

(b) *Classification*. Class II. The special controls for this device are FDA's:

(1) "Use of International Standard ISO 10993 'Biological Evaluation of Medical Device—Part I: Evaluation and Testing,'"

(2) "Guidance for the Content of 510(k)s for Conventional and High Permeability Hemodialyzers,"

(3) "Guidance for Industry and CDRH Reviewers on the Content of Pre-market Notifications for Hemodialysis Delivery Systems,"

(4) "Guidance for the Content of Pre-market Notifications for Water Purification Components and Systems for Hemodialysis," and

(5) "Guidance for Hemodialyzer Reuse Labeling."

[65 FR 17145, Mar. 31, 2000]

**§ 876.5870 Sorbent hemoperfusion system.**

(a) *Identification*. A sorbent hemoperfusion system is a device that consists of an extracorporeal blood system similar to that identified in the hemodialysis system and accessories (§ 876.5820) and a container filled with adsorbent material that removes a wide range of substances, both toxic and normal, from blood flowing through it. The adsorbent materials are usually activated-carbon or resins which may be coated or immobilized to prevent fine particles entering the patient's blood. The generic type of device may include lines and filters specifically designed to connect the device to the extracorporeal blood system. The device is used in the treatment of poisoning, drug overdose, hepatic coma, or metabolic disturbances.

(b) *Classification*. Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required*. No effective date has been established of the requirement for premarket approval. See § 876.3.

[48 FR 53023, Nov. 23, 1983, as amended at 52 FR 17738, May 11, 1987]

**§ 876.5880 Isolated kidney perfusion and transport system and accessories.**

(a) *Identification*. An isolated kidney perfusion and transport system and accessories is a device that is used to support a donated or a cadaver kidney and to maintain the organ in a near-normal physiologic state until it is transplanted into a recipient patient. This generic type of device may include tubing, catheters, connectors, an ice storage or freezing container with or without bag or preservatives, pulsatile or nonpulsatile hypothermic isolated organ perfusion apparatus